Special 510(k) Summary

SUBMITTER:

LIFEBRIDGE® Medizintechnik AG
Simon-Ohm-Str 1
84539 Ampfing Germany

DEC 27 2010

CONTACT PERSON:

Kathleen Johnson
Medical Device Approvals, Inc.
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DATE PREPARED: November 26, 2010

DEVICE TRADE NAME: LIFEBRIDGE SYSTEM

COMMON/USUAL NAME: Cardiopulmonary Support System

CLASSIFICATION: Class III per 21 CFR 870.4360

PRODUCT CODE: KFM

CLASSIFICATION NAMES:

Cardiopulmonary bypass heart/lung machine console (21 CFR 870.4220)
Non-roller type cardiopulmonary bypass blood pump (21 CFR 870.4360)
Cardiopulmonary bypass vascular catheter, cannulae, or tubing (21 CFR 870.4210)
Cardiopulmonary bypass adaptor, stopcock, manifold, or fitting (21 CFR 870.4290)
Cardiopulmonary bypass blood reservoir (21 CFR 870.4400)
Cardiopulmonary bypass pump speed control (21 CFR 870.4380)
Cardiopulmonary bypass oxygenator (21 CFR 870.4350)
Cardiopulmonary bypass heat exchanger (21 CFR 870.4240)
Cardiopulmonary bypass arterial line blood filter (21 CFR 870.4260)
Cardiopulmonary bypass level sensing monitor and/or control (21 CFR 870.4340)
Cardiopulmonary bypass bubble detector (21 CFR 870.4205)

PREDICATE DEVICES:
Lifebridge B2T System K090006
Medtronic Affinity NT oxygenator with Carmeda Bioactive Surface K000430
Avecor Affinity Hollow Fiber oxygenator with Trillium Biopassive Surface K973760

DEVICE DESCRIPTION:

The LIFEBRIDGE SYSTEM is a compact, pre-assembled, modular system consisting of:

1. Patient module housing an extracorporeal circuit comprised of several previously 510k-cleared devices. The circuit includes a rigid reservoir bag, a centrifugal pump, oxygenator, arterial filter, active air management system, tubing and connectors.

2. Sensors, including flow, pressure, level and bubble to read system parameters.

3. Control module that contains the electronics and user interface.

4. Base module that contains a touch screen, the main power connection and acts as a stable frame for the system.

The modification to the current Lifebridge System is to exchange the current oxygenator, BioCor 200, used in the patient module, for the Medtronic Affinity® NT oxygenator. The Affinity NT® Oxygenator is available with either a Carmeda® BioActive surface coating or a Trillium® Biopassive surface coating.

INDICATIONS FOR USE:

The LIFEBRIDGE SYSTEM is indicated for use as an extracorporeal blood oxygenation system for patients needing short term, 6 hours or less, cardiac and/or pulmonary support.

STATEMENT OF TECHNICAL CHARACTERISTICS COMPARISON:

This "Special 510(k)" is being submitted for a modification to the patient module of the Lifebridge System. The modification is to exchange one 510(k) cleared oxygenator for another. Both are hollow fiber membrane oxygenators cleared for short-term cardio-pulmonary support up to 6 hrs.

The major differences between the oxygenators are availability and a surface coating.

The Medtronic Affinity® NT oxygenator provides a surface coating to the large surface area of the oxygenator and the BioCor oxygenator does not. The coating can be either Carmeda® Bioactive Surface coating or Trillium Biopassive Surface coating.

The modification has been implemented through adherence to Design Controls. Risks posed by the change have been identified and analyzed. Measures to reduce any possible risks have been identified. Performance testing has been carried out to validate the mitigations and to ensure that the change to the patient module is safe, does not create any new risks and that performance of the modified module is equivalent to that of the original.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC 27 2010

Lifebridge Medizintechnik AG
c/o Ms. Kathleen Johnson
Medical Device Approvals, Inc.
1282 Round Hill Rd.
Bryn Mawr, PA 19010

Re: K103357
LIFEBRIDGE System
Regulation Number: 21 CFR 870.4360
Regulation Name: Non-roller type CPB Pump
Regulatory Class: Class III (three)
Product Code: KFM
Dated: December 13, 2010
Received: December 14, 2010

Dear Ms. Kathleen Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

FOR Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

K103357

DEC 27 2010

510(k) Number (if known):
Device Name: LIFEBRIDGE

Indications For Use: The LIFEBRIDGE is indicated for use as an extracorporeal blood oxygenation system for patients needing short term, 6 hours or less, cardiac and / or pulmonary support.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K103357